DEC 1 5 2011

K113107(pg 1/2)

5. 510(k) Summary

Contact:	Mr. Steve Banks Director
Prepared By:	Musculoskeletal Clinical Regulatory Advisers, LLC 1331 H Street, NW, 12th Floor Washington, DC 20005 Phone: (202) 552-5800 Fax: (202) 552-5798
Date Prepared:	October 19, 2011
Device Trade Name:	MSA Hip System
Manufacturer:	Global Manufacturing Technology 8-10 Resolution Drive Unanderra NSW 2526 AUSTRALIA Phone: (011) 61 (2) 8887 0100
Classification:	21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis Class II
Product Code:	MEH, LZO

Reason for Special 510(k) Submission:
The purpose of this Special 510(k) is to add ceramic femoral heads to the MSA Hip System. There have been no changes to the intended use of the device or its fundamental scientific technology.

Indications For Use:
The MSA Hip System is indicated for cementless use and is intended to replace a hip joint.

The device is intended for:

- skeletally mature individuals undergoing primary surgery for total hip replacement
- patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fracture of the femur.

- patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis
- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures

Device Description:
The MSA Hip System is a modular hip system consisting of a short stem which mates with a modular neck. The hip stems are made of Ti-6Al-4V (ASTM F136) with a commercially pure titanium plasma spray coating (ASTM F1580) on the proximal end. The stems are available with and without a hydroxyapatite coating. The modular necks are made of CoCr alloy (ASTM F1537). The MSA Hip System can be mated with metal or ceramic femoral heads and acetabular components.

Predicate Devices:
The modified MSA Hip System is substantially equivalent to the predicate MSA Hip System (K102172) with respect to indications, design, and function.

Substantial Equivalence:
The company performed burst strength testing of the ceramic femoral head. The test results demonstrate that the pre-determined acceptance criteria identified in the Design Control Activities Summary were met.

Conclusion
The MSA Hip System when mated with a ceramic femoral head is substantially equivalent to previously cleared devices with respect to its indications for use, design, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Global Manufacturing Technology
% Musculoskeletal Clinical Regulatory Advisers, LLC
Ms. Hollace Rhodes
Director, Orthopaedic Regulatory Affairs
1331 H St Northwest
Washington, DC 20005

DEC 15 2011

Re: K113107
Trade/Device Name: MSA Hip System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: MEH, LZO
Dated: November 16, 2011
Received: November 17, 2011

Dear Ms. Rhodes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K113107 (pg 1/1)

Device Name: MSA Hip System

The MSA Hip System is indicated for cementless use and is intended to replace a hip joint.

The device is intended for:

- skeletally mature individuals undergoing primary surgery for total hip replacement
- patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fracture of the femur.
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- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113107